A Study to Test the Safety and Efficacy of Sitagliptin Compared to Glimepiride in Patients With Type 2 Diabetes on a Stable Dose of Metformin (0431-803)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00701090

First received: June 17, 2008
Last updated: March 23, 2015
Last verified: March 2015
History of Changes

Purpose

A study to see if better control of type 2 diabetes can occur in patients taking a stable dose of metformin when they are also provided either sitagliptin or glimepiride. This study will also see if this treatment is safe and tolerable.

Condition	Intervention	Phase
Type 2 Diabetes Mellitus, Non Insulin Dependent. Diabetes Mellitus, Non-Insulin-Dependent	Drug: sitagliptin Drug: Comparator: glimepiride Drug: open-label metformin	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Phase III, Multicenter, Double-Blind, Randomized Study to Evaluate the Safety and Efficacy of the Addition of Sitagliptin Compared With the Addition of Glimepiride in Patients With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: Metformin Metformin hydrochloride Glimepiride Sitagliptin Sitagliptin phosphate

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Change From Baseline in HbA1c at Week 30 [Time Frame: Week 0 to Week 30] [Designated as safety issue: No]

  Patient-level HbA1c is measured as a percent. Thus, this change from baseline reflects the Week 30 HbA1c percent minus the Week 0 HbA1c percent.

Secondary Outcome Measures:

- Change From Baseline in FPG (Fasting Plasma Glucose) at Week 30 [Time Frame: Week 0 to Week 30] [Designated as safety issue: No]

  Change from baseline at Week 30 was defined as Week 30 minus Week 0.

- Percent of Patients With at Least One Hypoglycemia Episode of Any Type at Week 30 [Time Frame: Week 0 to Week 30] [Designated as safety issue: No]
- Change From Baseline in Body Weight at Week 30 [Time Frame: Week 0 to Week 30] [Designated as safety issue: No]

  Change from baseline at Week 30 was defined as Week 30 minus Week 0.

- Percent of Patients With A1C <7.0% at Week 30 [Time Frame: Week 30] [Designated as safety issue: No]
- Percent of Patients With A1C <6.5% at Week 30 [Time Frame: Week 30] [Designated as safety issue: No]

Enrollment:	1035
Study Start Date:	May 2008
Study Completion Date:	October 2009
Primary Completion Date:	October 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 sitagliptin	Drug: sitagliptin Sitagliptin 100 mg q.d. (q.d. = once daily); Duration of Treatment: 30 weeks Other Name: Januvia Drug: open-label metformin open-label metformin oral tablets (≥1500 mg/day) in addition to Glimepiride or Sitagliptin treatment. Other Name: metformin
Active Comparator: 2 glimepiride	Drug: Comparator: glimepiride glimepiride 1 mg per day to be up-titrated (up to week 18 of the double-blind treatment period) as considered appropriate by the investigator, based upon the results of patient's self blood glucose monitoring (SBGM). The maximum dose of glimepiride must not be higher than 6 mg/day. Drug: open-label metformin open-label metformin oral tablets (≥1500 mg/day) in addition to Glimepiride or Sitagliptin treatment. Other Name: metformin

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- 18 years or older
- Diagnosed with type 2 diabetes
- On a stable dose of metformin of at least 1500 mg per day

Exclusion Criteria:

- History of type 1 diabetes

Pregnant
- HIV positive
- On a weight loss program or medication
- Has a history of blood disorder, certain cancers, heart, liver or kidney disease

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00701090

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Additional Information:

MedWatch - FDA maintained medical product safety Information EXIT

Merck: Patient & Caregiver U.S. Product Web Site EXIT

Publications:

Arechavaleta R, Seck T, Chen Y, Krobot KJ, O'Neill EA, Duran L, Kaufman KD, Williams-Herman D, Goldstein BJ. Efficacy and safety of treatment with sitagliptin or glimepiride in patients with type 2 diabetes inadequately controlled on metformin monotherapy: a randomized, double-blind, non-inferiority trial. Diabetes Obes Metab. 2011 Feb;13(2):160-8. doi: 10.1111/j.1463-1326.2010.01334.x.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00701090 History of Changes
Other Study ID Numbers:	0431-803 2008_503
Study First Received:	June 17, 2008
Results First Received:	September 13, 2010
Last Updated:	March 23, 2015
Health Authority:	Austria: Federal Ministry for Health and Women

Keywords provided by Merck Sharp & Dohme Corp.:
Type 2 Diabetes Mellitus
Non Insulin Dependent

Additional relevant MeSH terms:

Diabetes Mellitus
Diabetes Mellitus, Type 2
Endocrine System Diseases
Glucose Metabolism Disorders
Metabolic Diseases
Glimepiride
Metformin
Sitagliptin
Anti-Arrhythmia Agents
Cardiovascular Agents
Dipeptidyl-Peptidase IV Inhibitors
Enzyme Inhibitors
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Hypoglycemic Agents
Immunologic Factors
Immunosuppressive Agents
Incretins
Molecular Mechanisms of Pharmacological Action
Pharmacologic Actions
Physiological Effects of Drugs
Protease Inhibitors
Therapeutic Uses

ClinicalTrials.gov processed this record on April 13, 2016

TO TOP

For Patients and Families | **For Researchers** | **For Study Record Managers**

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

A Study to Test the Safety and Efficacy of Sitagliptin Compared to Glimepiride in Patients With Type 2 Diabetes on a Stable Dose of Metformin (0431-803)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00701090

First received: June 17, 2008
Last updated: March 23, 2015
Last verified: March 2015
History of Changes

Results First Received: September 13, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Conditions:	Type 2 Diabetes Mellitus, Non Insulin Dependent. Diabetes Mellitus, Non-Insulin-Dependent
Interventions:	Drug: sitagliptin Drug: Comparator: glimepiride Drug: open-label metformin

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

Phase III

First Patient In: 14-May-2008; Last Patient Last Visit: 27-Oct-2009; 109 study centers worldwide

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

Patients at least 18 years of age with type 2 diabetes mellitus with inadequate glycemic control (A1C ≥6.5 and ≤9.0%) on a stable dose of metformin (at a dose of at least 1500 mg per day for at least 12 weeks) were eligible to enter the 30 week study. Up to a 2 week screening period, followed by a 2-week placebo run-in.

Reporting Groups

	Description
Sitagliptin	The Sitagliptin 100 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).
Glimepiride	The Glimepiride group includes data from patients randomized to receive treatment starting with 1 mg oral tablets of glimepiride (blinded) up-titrated until Week 18 as needed to a maximum dose of 6 mg q.d. in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).

Participant Flow: Overall Study

	Sitagliptin	Glimepiride
STARTED	**516**	**519**
COMPLETED	**468**	**468**
NOT COMPLETED	**48**	**51**
Adverse Event	**11**	**2**
Death	**0**	**1**
Lack of Efficacy	**5**	**4**
Lost to Follow-up	**9**	**9**
Physician Decision	**3**	**4**
Protocol Violation	**2**	**3**
Withdrawal by Subject	**11**	**16**
Other	**7**	**12**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Sitagliptin	The Sitagliptin 100 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).
Glimepiride	The Glimepiride group includes data from patients randomized to receive treatment starting with 1 mg oral tablets of glimepiride (blinded) up-titrated until Week 18 as needed to a maximum dose of 6 mg q.d. in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).

Total	Total of all reporting groups

Baseline Measures

	Sitagliptin	Glimepiride	Total
Number of Participants [units: participants]	**516**	**519**	**1035**
Age [units: years] Mean (Standard Deviation)	**56.3 (9.7)**	**56.2 (10.1)**	**56.3 (9.9)**
Gender [units: participants]			
Female	**232**	**240**	**472**
Male	**284**	**279**	**563**
Race/Ethnicity, Customized [units: participants]			
White	**297**	**298**	**595**
Black	**6**	**6**	**12**
Asian	**109**	**111**	**220**
American Indian/Alaska Native	**25**	**26**	**51**
Other	**79**	**78**	**157**
A1C (Hemoglobin A1c) [units: Percent] Mean (Standard Deviation)	**7.50 (0.70)**	**7.51 (0.76)**	**7.50 (0.73)**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in HbA1c at Week 30 [Time Frame: Week 0 to Week 30]

Measure Type	Primary
Measure Title	Change From Baseline in HbA1c at Week 30
Measure Description	Patient-level HbA1c is measured as a percent. Thus, this change from baseline reflects the Week 30 HbA1c percent minus the Week 0 HbA1c percent.
Time Frame	Week 0 to Week 30
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The per protocol population included all patients with a baseline value, a measurement at Week 30, and no major protocol violations (i.e., drug compliance <85%, use of prohibited medications, change of Metformin dose, incorrect double-blind study medication).

Reporting Groups

	Description
Sitagliptin	The Sitagliptin 100 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).
Glimepiride	The Glimepiride group includes data from patients randomized to receive treatment starting with 1 mg oral tablets of glimepiride (blinded) up-titrated until Week 18 as needed to a maximum dose of 6 mg q.d. in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).

Measured Values

	Sitagliptin	Glimepiride
Number of Participants Analyzed [units: participants]	**443**	**436**
Change From Baseline in HbA1c at Week 30 [units: Percent] Least Squares Mean (95% Confidence Interval)	**-0.47 (-0.55 to -0.39)**	**-0.54 (-0.62 to -0.45)**

Statistical Analysis 1 for Change From Baseline in HbA1c at Week 30

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Mean Difference (Net) [3]	0.07
Standard Deviation	(0.70)
95% Confidence Interval	-0.03 to 0.16

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	The pre-specified non-inferiority margin was 0.4%, i.e., Sitagliptin was declared non-inferior to glimepiride if the upper limit of the two-sided 95% confidence interval for the between group difference (sitagliptin minus glimepiride) was less than 0.4%
[3]	Other relevant estimation information:
	ANCOVA model with terms: treatment, country, and baseline HbA1c.

2. Secondary: Change From Baseline in FPG (Fasting Plasma Glucose) at Week 30 [Time Frame: Week 0 to Week 30]

Measure Type	Secondary
Measure Title	Change From Baseline in FPG (Fasting Plasma Glucose) at Week 30
Measure Description	Change from baseline at Week 30 was defined as Week 30 minus Week 0.
Time Frame	Week 0 to Week 30
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.
The per protocol population included all patients with a baseline value, a measurement at Week 30, and no major protocol violations (i.e., drug compliance <85%, use of prohibited medications, change of Metformin dose, incorrect double-blind study medication).

Reporting Groups

	Description
Sitagliptin	The Sitagliptin 100 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).
Glimepiride	The Glimepiride group includes data from patients randomized to receive treatment starting with 1 mg oral tablets of glimepiride (blinded) up-titrated until Week 18 as needed to a maximum dose of 6 mg q.d. in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).

Measured Values

	Sitagliptin	**Glimepiride**
Number of Participants Analyzed [units: participants]	**446**	**444**
Change From Baseline in FPG (Fasting Plasma Glucose) at Week 30 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-14.6 (-17.9 to -11.2)**	**-17.5 (-20.8 to -14.1)**

Statistical Analysis 1 for Change From Baseline in FPG (Fasting Plasma Glucose) at Week 30

Groups [1]	All groups
Mean Difference (Net) [2]	2.9
Standard Deviation	(28.8)
95% Confidence Interval	-0.9 to 6.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	ANCOVA model terms: treatment, country, and baseline.

3. Secondary: Percent of Patients With at Least One Hypoglycemia Episode of Any Type at Week 30 [Time Frame: Week 0 to Week 30]

Measure Type	Secondary
Measure Title	Percent of Patients With at Least One Hypoglycemia Episode of Any Type at Week 30
Measure Description	No text entered.
Time Frame	Week 0 to Week 30
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took at least one dose of study therapy.

Reporting Groups

	Description
Sitagliptin	The Sitagliptin 100 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).
Glimepiride	The Glimepiride group includes data from patients randomized to receive treatment starting with 1 mg oral tablets of glimepiride (blinded) up-titrated until Week 18 as needed to a maximum dose of 6 mg q.d. in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).

Measured Values

	Sitagliptin	**Glimepiride**
Number of Participants Analyzed [units: participants]	**516**	**518**
Percent of Patients With at Least One Hypoglycemia Episode of Any Type at Week 30 [units: Percentage of Participants]	**7.0**	**22.0**

Statistical Analysis 1 for Percent of Patients With at Least One Hypoglycemia Episode of Any Type at Week 30

Groups [1]	All groups
Method [2]	Miettinen &Nurminen method
P Value [3]	<0.001
Risk Difference (RD) [4]	-15.0
95% Confidence Interval	-19.3 to -10.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Miettinen &Nurminen method was used for the 95% confidence interval

4. Secondary: Change From Baseline in Body Weight at Week 30 [Time Frame: Week 0 to Week 30]

Measure Type	Secondary
Measure Title	Change From Baseline in Body Weight at Week 30

Measure Description	Change from baseline at Week 30 was defined as Week 30 minus Week 0.
Time Frame	Week 0 to Week 30
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who took at least one dose of study therapy and had body weight measurements at both baseline and Week 30.

Reporting Groups

	Description
Sitagliptin	The Sitagliptin 100 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).
Glimepiride	The Glimepiride group includes data from patients randomized to receive treatment starting with 1 mg oral tablets of glimepiride (blinded) up-titrated until Week 18 as needed to a maximum dose of 6 mg q.d. in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).

Measured Values

	Sitagliptin	**Glimepiride**
Number of Participants Analyzed [units: participants]	**465**	**461**
Change From Baseline in Body Weight at Week 30 **[units: Kilograms]** **Least Squares Mean (95% Confidence Interval)**	**-0.8 (-1.1 to -0.5)**	**1.2 (0.9 to 1.5)**

Statistical Analysis 1 for Change From Baseline in Body Weight at Week 30

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-2.0
Standard Deviation	(2.9)
95% Confidence Interval	-2.3 to -1.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: treatment, country, and baseline.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

[4]	Other relevant estimation information:
	ANCOVA model terms: treatment, country, and baseline.

5. Secondary: Percent of Patients With A1C <7.0% at Week 30 [Time Frame: Week 30]

Measure Type	Secondary
Measure Title	Percent of Patients With A1C <7.0% at Week 30
Measure Description	No text entered.
Time Frame	Week 30
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The per protocol population included all patients with a baseline value, a measurement at Week 30, and no major protocol violations (i.e., drug compliance <85%, use of prohibited medications, change of Metformin dose, incorrect double-blind study medication).

Reporting Groups

	Description
Sitagliptin	The Sitagliptin 100 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).
Glimepiride	The Glimepiride group includes data from patients randomized to receive treatment starting with 1 mg oral tablets of glimepiride (blinded) up-titrated until Week 18 as needed to a maximum dose of 6 mg q.d. in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).

Measured Values

	Sitagliptin	**Glimepiride**
Number of Participants Analyzed [units: participants]	**443**	**436**
Percent of Patients With A1C <7.0% at Week 30 [units: Percentage of Participants]	**52.4**	**59.6**

Statistical Analysis 1 for Percent of Patients With A1C <7.0% at Week 30

Groups [1]	All groups
Odds Ratio (OR) [2]	0.65
95% Confidence Interval	0.47 to 0.90

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:

	The parameter estimate and 95% CI represent the odds of having A1C <7.0% at Week 30 in the Sitagliptin group vs. the Glimepiride group, computed using a logistic regression model controlling for treatment, country and baseline A1C.

6. Secondary: Percent of Patients With A1C <6.5% at Week 30 [Time Frame: Week 30]

Measure Type	Secondary
Measure Title	Percent of Patients With A1C <6.5% at Week 30
Measure Description	No text entered.
Time Frame	Week 30
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The per protocol population included all patients with a baseline value, a measurement at Week 30, and no major protocol violations (i.e., drug compliance <85%, use of prohibited medications, change of Metformin dose, incorrect double-blind study medication).

Reporting Groups

	Description
Sitagliptin	The Sitagliptin 100 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).
Glimepiride	The Glimepiride group includes data from patients randomized to receive treatment starting with 1 mg oral tablets of glimepiride (blinded) up-titrated until Week 18 as needed to a maximum dose of 6 mg q.d. in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).

Measured Values

	Sitagliptin	**Glimepiride**
Number of Participants Analyzed [units: participants]	**443**	**436**
Percent of Patients With A1C <6.5% at Week 30 [units: Percentage of Participants]	**21.2**	**27.5**

Statistical Analysis 1 for Percent of Patients With A1C <6.5% at Week 30

Groups [1]	All groups
Odds Ratio (OR) [2]	0.67
95% Confidence Interval	0.47 to 0.95

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	The parameter estimate and 95% CI represent the odds of having A1C <6.5% at Week 30 in the Sitagliptin group vs. the Glimepiride

group, computed using a logistic regression model controlling for treatment, country and baseline A1C.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Particpants analyzed are those who received at least 1 dose of study medication. One participant in the Glimepiride group did not receive any study medication and is not included in the analysis.

Reporting Groups

	Description
Sitagliptin	The Sitagliptin 100 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).
Glimepiride	The Glimepiride group includes data from patients randomized to receive treatment starting with 1 mg oral tablets of glimepiride (blinded) up-titrated until Week 18 as needed to a maximum dose of 6 mg q.d. in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).

Serious Adverse Events

	Sitagliptin	Glimepiride
Total, serious adverse events		
# participants affected / at risk	**16/516 (3.10%)**	**11/518 (2.12%)**
Blood and lymphatic system disorders		
Thrombocytopenia [*1]		
# participants affected / at risk	**1/516 (0.19%)**	**0/518 (0.00%)**
Cardiac disorders		
Acute coronary syndrome [*1]		
# participants affected / at risk	**0/516 (0.00%)**	**1/518 (0.19%)**
Coronary artery disease [*1]		
# participants affected / at risk	**0/516 (0.00%)**	**1/518 (0.19%)**
Myocardial ischaemia [*1]		
# participants affected / at risk	**2/516 (0.39%)**	**0/518 (0.00%)**
Gastrointestinal disorders		
Inguinal hernia [*1]		
# participants affected / at risk	**1/516 (0.19%)**	**0/518 (0.00%)**
General disorders		
Non-cardiac chest pain [*1]		
# participants affected / at risk	**0/516 (0.00%)**	**1/518 (0.19%)**
Pain [*1]		
# participants affected / at risk	**0/516 (0.00%)**	**1/518 (0.19%)**

Infections and infestations		
Anal abscess [*1]		
# participants affected / at risk	**0/516 (0.00%)**	**1/518 (0.19%)**
Infection [*1]		
# participants affected / at risk	**0/516 (0.00%)**	**1/518 (0.19%)**
Mastitis [*1]		
# participants affected / at risk	**1/516 (0.19%)**	**0/518 (0.00%)**
Peritonsillar abscess [*1]		
# participants affected / at risk	**1/516 (0.19%)**	**0/518 (0.00%)**
Pneumonia [*1]		
# participants affected / at risk	**0/516 (0.00%)**	**1/518 (0.19%)**
Typhoid fever [*1]		
# participants affected / at risk	**1/516 (0.19%)**	**0/518 (0.00%)**
Injury, poisoning and procedural complications		
Clavicle fracture [*1]		
# participants affected / at risk	**0/516 (0.00%)**	**1/518 (0.19%)**
Humerus fracture [*1]		
# participants affected / at risk	**1/516 (0.19%)**	**0/518 (0.00%)**
Patella fracture [*1]		
# participants affected / at risk	**1/516 (0.19%)**	**0/518 (0.00%)**
Skin laceration [*1]		
# participants affected / at risk	**1/516 (0.19%)**	**0/518 (0.00%)**
Metabolism and nutrition disorders		
Diabetes mellitus inadequate control [*1]		
# participants affected / at risk	**1/516 (0.19%)**	**0/518 (0.00%)**
Musculoskeletal and connective tissue disorders		
Osteoarthritis [*1]		
# participants affected / at risk	**1/516 (0.19%)**	**1/518 (0.19%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Basal cell carcinoma [*1]		
# participants affected / at risk	**0/516 (0.00%)**	**1/518 (0.19%)**
Lung squamous cell carcinoma stage unspecified [*1]		
# participants affected / at risk	**1/516 (0.19%)**	**0/518 (0.00%)**
Pancreatic carcinoma [*1]		
# participants affected / at risk	**1/516 (0.19%)**	**0/518 (0.00%)**
Nervous system disorders		
Autonomic neuropathy [*1]		
# participants affected / at risk	**1/516 (0.19%)**	**0/518 (0.00%)**
Cerebrovascular accident [*1]		
# participants affected / at risk	**0/516 (0.00%)**	**1/518 (0.19%)**

Haemorrhagic stroke * 1		
# participants affected / at risk	**0/516 (0.00%)**	**1/518 (0.19%)**
Syncope * 1		
# participants affected / at risk	**0/516 (0.00%)**	**1/518 (0.19%)**
Respiratory, thoracic and mediastinal disorders		
Prostatitis * 1		
# participants affected / at risk	**1/516 (0.19%)**	**0/518 (0.00%)**
Vascular disorders		
Hypertension * 1		
# participants affected / at risk	**1/516 (0.19%)**	**0/518 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA (12.1)

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Particpants analyzed are those who received at least 1 dose of study medication. One participant in the Glimepiride group did not receive any study medication and is not included in the analysis.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sitagliptin	The Sitagliptin 100 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).
Glimepiride	The Glimepiride group includes data from patients randomized to receive treatment starting with 1 mg oral tablets of glimepiride (blinded) up-titrated until Week 18 as needed to a maximum dose of 6 mg q.d. in addition to ongoing treatment with open-label metformin oral tablets (≥1500 mg/day).

Other Adverse Events

	Sitagliptin	**Glimepiride**
Total, other (not including serious) adverse events		
# participants affected / at risk	**58/519 (11.18%)**	**134/518 (25.87%)**
Infections and infestations		
Nasopharyngitis * 1		
# participants affected / at risk	**25/519 (4.82%)**	**36/518 (6.95%)**
Metabolism and nutrition disorders		
Hypoglycaemia * 1		

# participants affected / at risk	36/519 (6.94%)	114/518 (22.01%)

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA (12.1)

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: Merck agreements may vary with individual investigators, but will not prohibit any investigator from publishing. Merck supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

Publications of Results:

Arechavaleta R, Seck T, Chen Y, Krobot KJ, O'Neill EA, Duran L, Kaufman KD, Williams-Herman D, Goldstein BJ. Efficacy and safety of treatment with sitagliptin or glimepiride in patients with type 2 diabetes inadequately controlled on metformin monotherapy: a randomized, double-blind, non-inferiority trial. Diabetes Obes Metab. 2011 Feb;13(2):160-8. doi: 10.1111/j.1463-1326.2010.01334.x.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00701090 History of Changes
Other Study ID Numbers: 0431-803
2008_503
Study First Received: June 17, 2008
Results First Received: September 13, 2010

Last Updated:	March 23, 2015
Health Authority:	Austria: Federal Ministry for Health and Women

TO TOP

For Patients and Families | **For Researchers** | **For Study Record Managers**

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK